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# COMMISSION DIRECTIVE 95/31/EC

## of 5 July 1995

## laying down specific criteria of purity concerning sweeteners for use in foodstuffs

**(Text with EEA relevance)**

(OJ L 178, 28.7.1995, p. 1)

Amended by:

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| | | No | page | date |
| ►M1 | Commission Directive 98/66/EC of 4 September 1998 | L 257 | 35 | 19.9.1998 |
| ►M2 | Commission Directive 2000/51/EC of 26 July 2000 | L 198 | 41 | 4.8.2000 |
| ►M3 | Commission Directive 2001/52/EC of 3 July 2001 | L 190 | 18 | 12.7.2001 |
| ►M4 | Commission Directive 2004/46/EC of 16 April 2004 | L 114 | 15 | 21.4.2004 |
| ►M5 | Commission Directive 2006/128/EC of 8 December 2006 | L 346 | 6 | 9.12.2006 |

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# COMMISSION DIRECTIVE 95/31/EC

**of 5 July 1995**

**laying down specific criteria of purity concerning sweeteners for use in foodstuffs**

**(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption ([1]), as amended by Directive 94/34/EC ([2]), and in particular Article 3 (3) (a) thereof,

After consultation of the Scientific Committee on Food,

Whereas it is necessary to establish purity criteria for all sweeteners mentioned in European Parliament and Council Directive 94/35/EC of 30 June 1994 on sweeteners for use in foodstuffs ([3]);

Whereas it is necessary to take into account the specifications and analytical techniques for sweeteners as set out in the *Codex Alimentarius* and the Joint FAO/WHO Expert Committee on Food Additives (Jecfa);

Whereas food additives, prepared by production methods or starting materials significantly different from those included in the evaluation of the Scientific Committee for Food, or different from those mentioned in this Directive, should be submitted for evaluation by the Scientific Committee for Food with a view to full evaluation with emphasis on the purity criteria;

Whereas the measures provided for in this Directive are in line with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

1. Purity criteria mentioned under Article 3 (3) (a) of Directive 89/107/EEC for sweeteners mentioned in Directive 94/35/EC are set out in the Annex.

2. The purity criteria for E 420 (i), E 420 (ii) and E 421 mentioned in the Annex to this Directive supersede the purity criteria for the said substances mentioned in the Annex to Council Directive 78/663/EEC ([4]).

*Article 2*

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 1 July 1996. They shall forthwith inform the Commission thereof.

([1]) OJ No L 40, 11. 2. 1989, p. 27.
([2]) OJ No L 237, 10. 9. 1994, p. 1.
([3]) OJ No L 237, 10. 9. 1994, p. 3.
([4]) OJ No L 223, 14. 8. 1978, p. 7.

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When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

2. Products put on the market or labelled before that date which do not comply with this Directive may, however, be marketed until stocks are exhausted.

*Article 3*

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Communities*.

*Article 4*

This Directive is addressed to the Member States.

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*ANNEX*

**E 420 (i) — SORBITOL**

| | |
|---|---|
| **Synonyms** | D-glucitol, D-sorbitol |
| **Definition** | |
| *Chemical name* | D-glucitol |
| *Einecs* | 200-061-5 |
| *E number* | E 420 (i) |
| *Chemical formula* | $C_6H_{14}O_6$ |
| *Relative molecular mass* | 182,17 |
| *Assay* | Content not less than 97% of total glycitols and not less than 91% of D-sorbitol on the dry weight basis.<br>Glycitols are compounds with the structural formula $CH_2OH$-$(CHOH)_n$-$CH_2OH$, where '*n*' is an integer |
| **Description** | White hygroscopic powder, crystalline powder, flakes or granules having a sweet taste |
| **Identification** | |
| *A. Solubility* | Very soluble in water, slightly soluble in ethanol |
| *B. Melting range* | 88 to 102°C |
| *C. Sorbitol monobenzylidene derivative* | To 5 g of the sample add 7 ml of methanol, 1 ml of benzaldehyde and 1 ml of hydrochloric acid. Mix and shake in a mechanical shaker until crystals appear. Filter with the aid of suction, dissolve the crystals in 20 ml of boiling water containing 1 g of sodium bicarbonate, filter while hot, cool the filtrate, filter with suction, wash with 5 ml of methanol-water mixture (1 in 2) and dry in air. The crystals so obtained melt between 173 and 179°C |
| **Purity** | |
| *Water content* | Not more than 1% (Karl Fischer method) |
| *Sulphated ash* | Not more than 0,1% expressed on dry weight basis |
| *Reducing sugars* | Not more than 0,3% expressed as glucose on dry weight basis |
| *Total sugars* | Not more than 1% expressed as glucose on dry weight basis |
| *Chlorides* | Not more than 50 mg/kg expressed on dry weight basis |
| *Sulphates* | Not more than 100 mg/kg expressed on dry weight basis |
| *Nickel* | Not more than 2 mg/kg expressed on dry weight basis |
| *Arsenic* | Not more than 3 mg/kg expressed on dry weight basis |
| *Lead* | Not more than 1 mg/kg expressed on dry weight basis |
| *Heavy metals* | Not more than 10 mg/kg expressed as Pb on dry weight basis |

**E 420 (ii) — SORBITOL SYRUP**

| | |
|---|---|
| **Synonyms** | D-clucitol syrup |
| **Definition** | |
| *Chemical name* | Sorbitol syrup formed by hydrogenation of glucose syrup is composed of D-sorbitol, D-mannitol and hydrogenated saccharides.<br>The part of the product which is not D-sorbitol is composed mainly of hydrogenated oligosaccharides formed by the hydrogenation of glucose syrup used as raw material (in which case the syrup is non-crystallizing) or mannitol. Minor quantities of glycitols where $n \leq 4$ may be present. Glycitols are compounds with the structural formula $CH_2OH$-$(CHOH)_n$-$CH_2OH$, where '*n*' is an integer |
| *Einecs* | 270-337-8 |
| *E number* | E 420 (ii) |
| *Assay* | Content not less than 69% total solids and not less than 50% of D-sorbitol on the anhydrous basis |
| **Description** | Clear colourless and sweet tasting aqueous solution |

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| | |
|---|---|
| **Identification** | |
| *A. Solubility* | Miscible with water, with glycerol, and with propane-1,2-diol |
| *B. Sorbitol monobenzylidene derivative* | To 5 g of the sample add 7 ml of methanol, 1 ml of benzaldehyde and 1 ml of hydrochloric acid. Mix and shake in a mechanical shaker until crystals appear. Filter with the aid of suction, dissolve the crystals in 20 ml of boiling water containing 1 g of sodium bicarbonate, filter while hot. Cool the filtrate filter with suction, wash with 5 ml of methanol-water mixture (1 in 2) and dry in air. The crystals so obtained melt between 173 and 179°C |
| **Purity** | |
| *Water content* | Not more than 31% (Karl Fischer method) |
| *Sulphated ash* | Not more than 0,1% expressed on dry weight basis |
| *Reducing sugars* | Not more than 0,3% expressed as glucose on dry weight basis |
| *Chlorides* | Not more than 50 mg/kg expressed on dry weight basis |
| *Sulphates* | Not more than 100 mg/kg expressed on dry weight basis |
| *Nickel* | Not more than 2 mg/kg expressed on dry weight basis |
| *Arsenic* | Not more than 3 mg/kg expressed on dry weight basis |
| *Lead* | Not more than 1 mg/kg expressed on dry weight basis |
| *Heavy metals* | Not more than 10 mg/kg expressed as Pb on dry weight basis |

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**E 421 MANNITOL**

| | |
|---|---|
| 1. **Mannitol** | |
| **Synonyms** | D-mannitol |
| **Definition** | Manufactured by catalytic hydrogenation of carbohydrate solutions containing glucose and/or fructose |
| Chemical name | D-mannitol |
| Einecs | 200-711-8 |
| Chemical formula | $C_6H_{14}O_6$ |
| Molecular weight | 182,2 |
| Assay | Content not less than 96,0 % D-mannitol and not more than 102 % on the dried basis |
| **Description** | White, odourless, crystalline powder |
| **Identification** | |
| A. Solubility | Soluble in water, very slightly soluble in ethanol, practically insoluble in ether |
| B. Melting range | Between 164 and 169 °C |
| C. Thin layer chromatography | Passes test |
| D. Specific rotation | $[\alpha]\ ^{20}_{D}$: + 23° to + 25° (borate solution) |
| E. pH | Between 5 and 8<br>Add 0,5 ml of a saturated solution of potassium chloride to 10 ml of a 10 % w/v solution of the sample, then measure the pH |
| **Purity** | |
| Loss on drying | Not more than 0,3 % (105 °C, four hours) |
| Reducing sugars | Not more than 0,3 % (as glucose) |
| Total sugars | Not more than 1 % (as glucose) |
| Sulphated ash | Not more than 0,1 % |
| Chlorides | Not more than 70 mg/kg |
| Sulphate | Not more than 100 mg/kg |
| Nickel | Not more than 2 mg/kg |
| Lead | Not more than 1 mg/kg |
| 2 **Mannitol manufactured by fermentation** | |
| **Synonyms** | D-mannitol |

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| | |
|---|---|
| **Definition** | Manufactured by discontinous fermentation under aerobic conditions using a conventional strain of the yeast *Zygosaccharomyces rouxii* |
| Chemical name | D-mannitol |
| Einecs | 200-711-8 |
| Chemical formula | $C_6H_{14}O_6$ |
| Molecular weight | 182,2 |
| Assay | Not less than 99 % on the dried basis |
| **Description** | White, odourless crystalline powder |
| **Identification** | |
| A. Solubility | Soluble in water, very slightly soluble in ethanol, practically insoluble in ether |
| B. Melting range | Between 164 and 169 °C |
| C. Thin layer chromatography | passes test |
| D. Specific rotation | $[\alpha]\ ^{20}_{D}$: + 23° to + 25° (borate solution) |
| E. pH | Between 5 and 8<br>Add 0,5 ml of a saturated solution of potassium chloride to 10 ml of a 10 % w/v solution of the sample, then measure the pH |
| **Purity** | |
| Arabitol | Not more than 0,3 % |
| Loss on drying | Not more than 0,3 % (105 °C, four hours) |
| Reducing sugars | Not more than 0,3 % (as glucose) |
| Total sugars | Not more than 1 % (as glucose) |
| Sulphated ash | Not more than 0,1 % |
| Chlorides | Not more than 70 mg/kg |
| Sulphate | Not more than 100 mg/kg |
| Lead | Not more than 1 mg/kg |
| Aerobic mesophilic bacteria | Not more than $10^3$/g |
| Coliforms | Absent in 10 g |
| *Salmonella* | Absent in 10 g |
| *E. coli* | Absent in 10 g |
| *Staphylococcus aureus* | Absent in 10 g |
| *Pseudomonas aeruginosa* | Absent in 10 g |
| Moulds | Not more than 100/g |
| Yeasts | Not more than 100/g |

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**E 953 — ISOMALT**

| | |
|---|---|
| **Synonyms** | Hydrogenated isomaltulose, hydrogenated palatinose. |
| **Definition** | |
| *Chemical name* | Isomalt is a mixture of hydrogenated mono- and disaccharides whose principal components are the disaccharides: 6-O-α-D-Glucopyranosyl-D-sorbitol (1,6-GPS) and 1-O-α-D-Glucopyranosyl-D-mannitol dihydrate (1,1-GPM) |
| *Chemical formula* | 6-O-α-D-Glucopyranosyl-D-sorbitol: $C_{12}H_{24}O_{11}$<br>1-O-α-D-Glucopyranosyl-D-mannitol dihydrate: $C_{12}H_{24}O_{11}.2H_2O$ |
| *Relative molecular mass* | 6-O-α-D-Glucopyranosyl-D-sorbitol: 344,32<br>1-O-α-D-Glucopyranosyl-D-mannitol dihydrate: 380,32 |
| *Assay* | Content not less than 98 % of hydrogenated mono- and disaccharides and not less than 86 % of the mixture of 6-O-α-D-Glucopyranosyl-D-sorbitol and 1-O-α-D-Glucopyranosyl-D-mannitol dihydrate determined on the anhydrous basis. |
| **Description** | Odourless, white, slightly hygroscopic, crystalline mass. |

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|---|---|
| **Identification** | |
| A. *Solubility* | Soluble in water, very slightly soluble in ethanol. |
| B. *Thin layer chromatography* | Examine by thin layer chromatography using a plate coated with an approximately 0,2 mm layer of chromatographic silica gel. The principal spots in the chromatogram are those of 1,1-GPM and 1,6-GPS. |
| **Purity** | |
| *Water content* | Not more than 7 % (Karl Fischer Method) |
| *Sulphated ash* | Not more than 0,05 % expressed on the dry weight basis |
| *D-Mannitol* | Not more than 3 % |
| *D-Sorbitol* | Not more than 6 % |
| *Reducing sugars* | Not more than 0,3 % expressed as glucose on the dry weight basis |
| *Nickel* | Not more than 2 mg/kg expressed on the dry weight basis |
| *Arsenic* | Not more than 3 mg/kg expressed on the dry weight basis |
| *Lead* | Not more than 1 mg/kg expressed on the dry weight basis |
| *Heavy metals (as Pb)* | Not more than 10 mg/kg expressed on the dry weight basis. |

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**E 965 (i) MALTITOL**

| | |
|---|---|
| **Synonyms** | D-Maltitol, hydrogenated maltose |
| **Definition** | |
| Chemical name | (α)-D-Glucopyranosyl-1,4-D-glucitol |
| Einecs | 209-567-0 |
| Chemical formula | $C_{12}H_{24}O_{11}$ |
| Relative molecular mass | 344,31 |
| Assay | Content not less than 98 % of D-maltitol $C_{12}H_{24}O_{11}$ on the anhydrous basis |
| **Description** | Sweet tasting, white crystalline powder |
| **Identification** | |
| A. Solubility | Very soluble in water, slightly soluble in ethanol |
| B. Melting range | 148 to 151 °C |
| C. Specific rotation | $[\alpha]_D^{20}$ = + 105,5° to + 108,5° (5 % w/v solution) |
| **Purity** | |
| Water | Not more than 1 % (Karl Fischer method) |
| Sulphated ash | Not more than 0,1 % expressed on dry weight basis |
| Reducing sugars | Not more than 0,1 % expressed as glucose on dry weight basis |
| Chlorides | Not more than 50 mg/kg expressed on dry weight basis |
| Sulphates | Not more than 100 mg/kg expressed on dry weight basis |
| Nickel | Not more than 2 mg/kg expressed on dry weight basis |
| Arsenic | Not more than 3 mg/kg expressed on dry weight basis |
| Lead | Not more than 1 mg/kg expressed on dry weight basis |

**E 965 (ii) MALTITOL SYRUP**

| | |
|---|---|
| **Synonyms** | Hydrogenated high-maltose glucose syrup, hydrogenated glucose syrup |
| **Definition** | A mixture consisting of mainly maltitol with sorbitol and hydrogenated oligo- and polysaccharides. It is manufactured by the catalytic hydrogenation of high maltose-content glucose syrup or by the hydrogenation of its individual components followed by blending. The article of commerce is supplied both as a syrup and as a solid product |

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|---|---|
| Assay | Content not less than 99 % of total hydrogenated saccharides on the anhydrous basis and not less than 50 % of maltitol on the anhydrous basis |
| **Description** | Colourless and odourless, clear viscous liquids or white crystalline masses |
| **Identification** | |
| A. Solubility | Very soluble in water, slightly soluble in ethanol |
| B. Thin layer chromatography | Passes test |
| **Purity** | |
| Water | Not more than 31 % (Karl Fischer) |
| Reducing sugars | Not more than 0,3 % (as glucose) |
| Sulphated ash | Not more than 0,1 % |
| Chlorides | Not more than 50 mg/kg |
| Sulphate | Not more than 100 mg/kg |
| Nickel | Not more than 2 mg/kg |
| Lead | Not more than 1 mg/kg |

**E 966 LACTITOL**

| | |
|---|---|
| **Synonyms** | Lactit, lactositol, lactobiosit |
| **Definition** | |
| Chemical name | 4-O-β-D-Galactopyranosyl-D-glucitol |
| Einecs | 209-566-5 |
| Chemical formula | $C_{12}H_{24}O_{11}$ |
| Relative molecular mass | 344,32 |
| Assay | Not less than 95 % on the dry weight basis |
| **Description** | Sweet-tasting crystalline powders or colourless solutions. Crystalline products occur in anhydrous, monohydrate and dihydrate forms |
| **Identification** | |
| A. Solubility | Very soluble in water |
| B. Specific rotation | $[\alpha]_D^{20}$ = + 13° to + 16° calculated on the anhydrous basis (10 % w/v aqueous solution) |
| **Purity** | |
| Water | Crystalline products; not more than 10,5 % (Karl Fischer method) |
| Other polyols | Not more than 2,5 % on the anhydrous basis |
| Reducing sugars | Not more than 0,2 % expressed as glucose on dry weight basis |
| Chlorides | Not more than 100 mg/kg expressed on dry weight basis |
| Sulphates | Not more than 200 mg/kg expressed on dry weight basis |
| Sulphated ash | Not more than 0,1 % expressed on dry weight basis |
| Nickel | Not more than 2 mg/kg expressed on dry weight basis |
| Arsenic | Not more than 3 mg/kg expressed on dry weight basis |
| Lead | Not more than 1 mg/kg expressed on dry weight basis |

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**E 967 — XYLITOL**

| | |
|---|---|
| **Synonyms** | Xylitol |
| **Definition** | |
| *Chemical name* | D-xylitol |
| *Einecs* | 201-788-0 |
| *E number* | E 967 |
| *Chemical formula* | $C_5H_{12}O_5$ |
| *Relative molecular mass* | 152,15 |
| *Assay* | Not less than 98,5% as xylitol on the anhydrous basis |

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| | |
|---|---|
| **Description** | White, crystalline powder, practically odourless with a very sweet taste |
| **Identification** | |
| *A. Solubility* | Very soluble in water, sparingly soluble in ethanol |
| *B. Melting range* | 92 to 96°C |
| *C. pH* | 5 to 7 (10% w/v aqueous solution) |
| **Purity** | |
| *Loss on drying* | Not more than 0,5%. Dry 0,5 g of sample in a vacuum over phosphorus at 60°C for four hours |
| *Sulphated ash* | Not more than 0,1% expressed on dry weight basis |
| *Reducing sugars* | Not more than 0,2% expressed as glucose on dry weight basis |
| *Other polyhydric alcohols* | Not more than 1% expressed on dry weight basis |
| *Nickel* | Not more than 2 mg/kg expressed on dry weight basis |
| *Arsenic* | Not more than 3 mg/kg expressed on dry weight basis |
| *Lead* | Not more than 1 mg/kg expressed on dry weight basis |
| *Heavy metals* | Not more than 10 mg/kg expressed as Pb on dry weight basis |
| *Chlorides* | Not more than 100 mg/kg expressed on dry weight basis |
| *Sulphates* | Not more than 200 mg/kg expressed on dry weight basis |

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**E 968 ERYTHRITOL**

| | |
|---|---|
| **Synonyms** | Meso-erythritol, tetrahydroxybutane, erythrite |
| **Definition** | Obtained by fermentation of carbohydrate source by safe and suitable food grade osmophilic yeasts such as *Moniliella pollinis* or *Trichosporonoides megachilensis*, followed by purification and drying |
| Chemical name | 1,2,3,4-Butanetetrol |
| Einecs | 205-737-3 |
| Chemical formula | $C_4H_{10}O_4$ |
| Molecular weight | 122,12 |
| Assay | Not less than 99 % after drying |
| **Description** | White, odourless, non-hygroscopic, heat-stable crystals with a sweetness of approximately 60-80 % that of sucrose. |
| **Identification** | |
| A. Solubility | Freely soluble in water, slightly soluble in ethanol, insoluble in diethyl ether. |
| B. Melting range | 119-123 °C |
| **Purity** | |
| Loss on drying | Not more than 0,2 % (70 °C, six hours, in a vacuum desiccator) |
| Sulphated ash | Not more than 0,1 % |
| Reducing substances | Not more than 0,3 % expressed as D-glucose |
| Ribitol and glycerol | Not more than 0,1 % |
| Lead | Not more than 0,5 mg/kg |

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**E 950 — ACESULFAME K**

| | |
|---|---|
| **Synonyms** | Acesulfame potassium, potassium salt of 3,4-dihydro-6-methyl-1,2,3-oxathiazin-4-one, 2,2-dioxide |
| **Definition** | |
| Chemical name | 6-methyl-1,2,3-oxathiazin-4(3H)-one-2,2-dioxide potassium salt |
| Einecs | 259-715-3 |
| Chemical formula | $C_4H_4KNO_4S$ |
| Molecular weight | 201,24 |

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|---|---|
| Assay | Content not less than 99 % of $C_4H_4KNO_4S$ on the anhydrous basis |
| **Description** | Odourless, white, crystalline powder. Approximately 200 times as sweet as sucrose |
| **Identification** | |
| A. Solubility | Very soluble in water, very slightly soluble in ethanol |
| B. Ultra violet absorption | Maximum 227 ± 2 nm for a solution of 10 mg in 1 000 ml of water |
| C. Positive test for potassium | Passes test (test the residue obtained by igniting 2 g of the sample) |
| D. Precipitation test | Add a few drops of a 10 % solution of sodium cobaltnitrite to a solution of 0,2 g of the sample in 2 ml of acetic acid and 2 ml of water. A yellow precipitate is produced |
| **Purity** | |
| Loss on drying | Not more than 1 % (105 °C, two hours) |
| Organic impurities | Passes test for 20 mg/kg of UV active components |
| Fluoride | Not more than 3 mg/kg |
| Lead | Not more than 1 mg/kg |

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**E 951 — ASPARTAME**

| | |
|---|---|
| **Synonyms** | Aspartyl phenylalanine methyl ester |
| **Definition** | |
| *Chemical name* | N-L-α-(Aspartyl-L-phenylalanine-1-methyl ester, 3-amino-N-(α-carbomethoxy-phenethyl)-succinamic acid-N-methyl ester |
| *Einecs* | 245-261-3 |
| *E number* | E 951 |
| *Chemical formula* | $C_{14}H_{18}N_2O_5$ |
| *Relative molecular mass* | 294,31 |
| *Assay* | Not less than 98% and not more than 102% of $C_{14}H_{18}N_2O_5$ on the anhydrous basis |
| **Description** | White, odourless, crystalline powder having a sweet taste. Approximately 200 times as sweet as sucrose |
| **Identification** | |
| *Solubility* | Slightly soluble in water and in ethanol |
| **Purity** | |
| *Loss on drying* | Not more than 4,5% (105°C, four hours) |
| *Sulphated ash* | Not more than 0,2% expressed on dry weight basis |
| *pH* | Between 4,5 and 6,0 (1 in 125 solution) |
| *Transmittance* | The transmittance of a 1% solution in 2N hydrochloric acid, determined in a 1-cm cell at 430 nm with a suitable spectrophotometer, using 2N hydrochloric acid as a reference, is not less than 0,95, equivalent to an absorbance of not more than approximately 0,022 |
| *Specific rotation* | $(\alpha)_D^{20}$: +14,5 to +16,5°<br>Determine in a 4 in 100/15 N formic acid solution within 30 minutes after preparation of the sample solution |
| *Arsenic* | Not more than 3 mg/kg expressed on dry weight basis |
| *Lead* | Not more than 1 mg/kg expressed on dry weight basis |
| *Heavy metals* | Not more than 10 mg/kg expressed as Pb on dry weight basis |
| *5-Benzyl-3,6-dioxo-2-piperazineacetic acid* | Not more than 1,5% expressed on dry weight basis |

**E 952 — CYCLAMIC ACID AND ITS Na AND Ca SALTS**

| | |
|---|---|
| (I) CYCLAMIC ACID | |
| **Synonyms** | Cyclohexylsulphamic acid, cyclamate |

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|---|---|
| **Definition** | |
| *Chemical name* | Cyclohexanesulphamic acid, cyclohexylaminosulphonic acid |
| *Einecs* | 202-898-1 |
| *E number* | E 952 |
| *Chemical formula* | $C_6H_{13}NO_3S$ |
| *Relative molecular mass* | 179,24 |
| *Assay* | Cyclohexylsulphamic acid contains not less than 98% and not more than the equivalent of 102% of $C_6H_{13}NO_3S$, calculated on the anhydrous basis |
| **Description** | A practically colourless, white crystalline powder with a sweet-sour taste. Approximately 40 times as sweet as sucrose |
| **Identification** | |
| *A. Solubility* | Soluble in water and in ethanol |
| *B. Precipitation test* | Acidify a 2% solution with hydrochloric acid, add 1 ml of an approximately molar solution of barium chloride in water and filter if any haze or precipitate forms. To the clear solution add 1 ml of a 10% solution of sodium nitrite. A white precipitate forms. |
| **Purity** | |
| *Loss on drying* | Not more than 1% (105°C, one hour) |
| *Selenium* | Not more than 30 mg/kg expressed as selenium on dry weight basis |
| *Lead* | Not more than 1 mg/kg expressed on dry weight basis |
| *Heavy metals* | Not more than 10 mg/kg expressed as Pb on dry weight basis |
| *Arsenic* | Not more than 3 mg/kg expressed on dry weight basis |
| *Cyclohexylamine* | Not more than 10 mg/kg expressed on dry weight basis |
| *Dicyclohexylamine* | Not more than 1 mg/kg expressed on dry weight basis |
| *Aniline* | Not more than 1 mg/kg expressed on dry weight basis |
| (II) SODIUM CYCLAMATE | |
| **Synonyms** | Cyclamate, sodium salt of cyclamic acid |
| **Definition** | |
| *Chemical name* | Sodium cyclohexanesulphamate, sodium cyclohexylsulphamate |
| *Einecs* | 205-348-9 |
| *E number* | E 952 |
| *Chemical formula* | $C_6H_{12}NNaO_3S$ and the dihydrate form $C_6H_{12}NNaO_3S{\cdot}2H_2O$ |
| *Relative molecular mass* | 201,22 calculated on the anhydrous form<br>237,22 calculated on the hydrated form |
| *Assay* | Not les sthan 98% and not more than 102% on the dried basis<br>Dihydrate form: not less than 84% on the dried basis |
| **Description** | White, odourless crystals or crystalline powder. Approximately 30 times as sweet as sucrose |
| **Identification** | |
| *Solubility* | Soluble in water, practically insoluble in ethanol |
| **Purity** | |
| *Loss on drying* | Not more than 1% (105°C, one hour)<br>Not more than 15,2% (105°C, two hours) for the dihydrate form |
| *Selenium* | Not more than 30 mg/kg expressed as selenium on dry weight basis |
| *Arsenic* | Not more than 3 mg/kg expressed on dry weight basis |
| *Lead* | Not more than 1 mg/kg expressed on dry weight basis |
| *Heavy metals* | Not more than 10 mg/kg expressed as Pb on dry weight basis |
| *Cyclohexylamine* | Not more than 10 mg/kg expressed on dry weight basis |
| *Dicyclohexylamine* | Not more than 1 mg/kg expressed on dry weight basis |
| *Aniline* | Not more than 1 mg/kg expressed on dry weight basis |

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|---|---|
| (III) CALCIUM CYCLAMATE | |
| **Synonyms** | Cyclamate, calcium salt of cyclamic acid |
| **Definition** | |
| *Chemical name* | Calcium cyclohexanesulphamate, calcium cyclohexylsulphamate |
| *Einecs* | 205-349-4 |
| *E number* | E 952 |
| *Chemical formula* | $C_{12}H_{24}CaN_2O_6S_2 \cdot 2H_2O$ |
| *Relative molecular mass* | 432,57 |
| *Assay* | Not less than 98% and not more than 10% on the dried basis |
| **Description** | White, colourless crystals or crystaline powder. Approximately 30 times as sweet as sucrose |
| **Identification** | |
| *Solubility* | Soluble in water, sparingly soluble in ethanol |
| **Purity** | |
| *Loss on drying* | Not more than 1% (105°C, one hour)<br>Not more than 8,5% (140°C, four hours) for the dihydrate form |
| *Selenium* | Not more than 30 mg/kg expressed as selenium on dry weight basis |
| *Arsenic* | Not more than 3 mg/kg expressed on dry weight basis |
| *Lead* | Not more than 1 mg/kg expressed on dry weight basis |
| *Heavy metals* | Not more than 10 mg/kg expressed as Pb on dry weight basis |
| *Cyclohexylamine* | Not more than 10 mg/kg expressed on dry weight basis |
| *Dicyclohexylamine* | Not more than 1 mg/kg expressed on dry weight basis |
| *Aniline* | Not more than 1 mg/kg expressed on dry weight basis |

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**E 954 SACCHARIN AND ITS Na, K AND Ca SALTS**

| | |
|---|---|
| (I) *SACCHARIN* | |
| **Definition** | |
| Chemical name | 3-Oxo-2,3-dihydrobenzo(d)isothiazol-1,1-dioxide |
| Einecs | 201-321-0 |
| Chemical formula | $C_7H_5NO_3S$ |
| Relative molecular mass | 183,18 |
| Assay | Not less than 99 % and not more than 101 % of $C_7H_5NO_3S$ on the anhydrous basis |
| **Description** | White crystals or a white crystalline powder, odourless or with a faint, aromatic odour, having a sweet taste, even in very dilute solutions. Approximately between 300 and 500 times as sweet as sucrose |
| **Identification** | |
| Solubility | Slightly soluble in water, soluble in basic solutions, sparingly soluble in ethanol |
| **Purity** | |
| Loss on drying | Not more than 1 % (105 °C, two hours) |
| Melting range | 226-230 °C |
| Sulphated ash | Not more than 0,2 % expressed on dry weight basis |
| Benzoic and salicylic acid | To 10 ml of a 1 in 20 solution, previously acidified with five drops of acetic acid, add three drops of an approximately molar solution of ferric chloride in water. No precipitate or violet colour appears |
| o-Toluenesulphonamide | Not more than 10 mg/kg expressed on dry weight basis |
| p-Toluenesulphonamide | Not more than 10 mg/kg expressed on dry weight basis |
| Benzoic acid p-sulfonamide | Not more than 25 mg/kg expressed on dry weight basis |

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|---|---|
| Readily carbonisable substances | Absent |
| Arsenic | Not more than 3 mg/kg expressed on dry weight basis |
| Selenium | Not more than 30 mg/kg expressed on dry weight basis |
| Lead | Not more than 1 mg/kg expressed on dry weight basis. |

(II) *SODIUM SACCHARIN*

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|---|---|
| **Synonyms** | Saccharin, sodium salt of saccharin |
| **Definition** | |
| Chemical name | Sodium o-benzosulphimide, sodium salt of 2,3-dihydro-3-oxobenzisosulphonazole, oxobenzisosulphonazole, 1,2-benzisothiazolin-3-one-1,1-dioxide sodium salt dihydrate |
| Einecs | 204-886-1 |
| Chemical formula | $C_7H_4NNaO_3S \cdot 2H_2O$ |
| Relative molecular mass | 241,19 |
| Assay | Not less than 99 % and not more than 101 % of $C_7H_4NNaO_3S$ on the anhydrous basis |
| **Description** | White crystals or a white crystalline efflorescent powder, odourless or with a faint odour, having an intensely sweet taste, even in very dilute solutions. Approximately between 300 and 500 times as sweet as sucrose in dilute solutions |
| **Identification** | |
| Solubility | Freely soluble in water, sparingly soluble in ethanol |
| **Purity** | |
| Loss on drying | Not more than 15 % (120 °C, four hours) |
| Benzoic and salicylic acid | To 10 ml of a 1 in 20 solution, previously acidified with five drops of acetic acid, add three drops of an approximately molar solution of ferric chloride in water. No precipitate or violet colour appears |
| o-Toluenesulphonamide | Not more than 10 mg/kg expressed on dry weight basis |
| p-Toluenesulphonamide | Not more than 10 mg/kg expressed on dry weight basis |
| Benzoic acid p-sulphonamide | Not more than 25 mg/kg expressed on dry weight basis |
| Readily carbonisable substances | Absent |
| Arsenic | Not more than 3 mg/kg expressed on dry weight basis |
| Selenium | Not more than 30 mg/kg expressed on dry weight basis |
| Lead | Not more than 1 mg/kg expressed on dry weight basis |

(III) *CALCIUM SACCHARIN*

| | |
|---|---|
| **Synonyms** | Saccharin, calcium salt of saccharin |
| **Definition** | |
| Chemical name | Calcium o-benzosulphimide, calcium salt of 2,3-dihydro-3-oxobenzisosulfonazole, 1,2-benzisothiazolin-3-one-1,1-dioxide calcium salt hydrate (2:7) |
| Einecs | 229-349-9 |
| Chemical formula | $C_{14}H_8CaN_2O_6S_2 \cdot 3^1/_2H_2O$ |
| Relative molecular mass | 467,48 |
| Assay | Not less than 95 % of $C_{14}H_8CaN_2O_6S_2$ on the anhydrous basis |
| **Description** | White crystals or a white crystalline powder, odourless or with a faint odour, having an intensely sweet taste, even in very dilute solutions. Approximately between 300 and 500 times as sweet as sucrose in dilute solutions |
| **Identification** | |
| Solubility | Freely soluble in water, soluble in ethanol |

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|---|---|
| **Purity** | |
| Loss on drying | Not more than 13,5 % (120 °C, four hours) |
| Benzoic and salicylic acid | To 10 ml of a 1 in 20 solution, previously acidified with five drops of acetic acid, add three drops of an approximately molar solution of ferric chloride in water. No precipitate or violet colour appears |
| o-Toluenesulphonamide | Not more than 10 mg/kg expressed on dry weight basis |
| p-Toluenesulphonamide | Not more than 10 mg/kg expressed on dry weight basis |
| Benzoic acid p-sulphonamide | Not more than 25 mg/kg expressed on dry weight basis |
| Readily carbonisable substances | Absent |
| Arsenic | Not more than 3 mg/kg expressed on dry weight basis |
| Selenium | Not more than 30 mg/kg expressed on dry weight basis |
| Lead | Not more than 1 mg/kg expressed on dry weight basis |

(IV) *POTASSIUM SACCHARIN*

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|---|---|
| **Synonyms** | Saccharin, potassium salt of saccharin |
| **Definition** | |
| Chemical name | Potassium o-benzosulphimide, potassium salt of 2,3-dihydro-3-oxobenzisosulphonazole, potassium salt of 1,2-benzisothiazolin-3-one-1,1-dioxide monohydrate |
| Einecs | |
| Chemical formula | $C_7H_4KNO_3S \cdot H_2O$ |
| Relative molecular mass | 239,77 |
| Assay | Not less than 99 % and not more than 101 % of $C_7H_4KNO_3S$ on the anhydrous basis |
| **Description** | White crystals or a white crystalline powder, odourless or with a faint odour, having an intensely sweet taste, even in very dilute solutions. Approximately between 300 and 500 times as sweet as sucrose |
| **Identification** | |
| Solubility | Freely soluble in water, sparingly soluble in ethanol |
| **Purity** | |
| Loss on drying | Not more than 8 % (120 °C, four hours) |
| Benzoic and salicylic acid | To 10 ml of a 1 in 20 solution, previously acidified with five drops of acetic acid, add three drops of an approximately molar solution of ferric chloride in water. No precipitate or violet colour appears |
| o-Toluenesulphonamide | Not more than 10 mg/kg expressed on dry weight basis |
| p-Toluenesulphonamide | Not more than 10 mg/kg expressed on dry weight basis |
| Benzoic acid p-sulphonamide | Not more than 25 mg/kg expressed on dry weight basis |
| Readily carbonisable substances | Absent |
| Arsenic | Not more than 3 mg/kg expressed on dry weight basis |
| Selenium | Not more than 30 mg/kg expressed on dry weight basis |
| Lead | Not more than 1 mg/kg expressed on dry weight basis |

E 955 SUCRALOSE

| | |
|---|---|
| **Synonyms** | 4,1′,6′-Trichlorogalactosucrose |
| **Definition** | |
| Chemical name | 1,6-Dichloro-1,6-dideoxy-β-D-fructofuranosyl-4-chloro-4-deoxy-α-D-galactopyranoside |
| Einecs | 259-952-2 |
| Chemical formula | $C_{12}H_{19}Cl_3O_8$ |

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|---|---|
| Molecular weight | 397,64 |
| Assay | Content not less than 98 % and not more than 102 % of $C_{12}H_{19}Cl_3O_8$ calculated on an anhydrous basis. |
| **Description** | White to off-white, practically odourless crystalline powder. |
| **Identification** | |
| A. Solubility | Freely soluble in water, methanol and ethanol<br>Slightly soluble in ethyl acetate |
| B. Infrared absorption | The infrared spectrum of a potassium bromide dispersion of the sample exhibits relative maxima at similar wave numbers as those shown in the reference spectrum obtained using a sucralose reference standard |
| C. Thin layer chromatography | The main spot in the test solution has the same Rf value as that of the main spot of standard solution A referred to in the test for other chlorinated disaccharides. This standard solution is obtained by dissolving 1,0 g of sucralose reference standard in 10 ml of methanol |
| D. Specific rotation | $[\alpha]_D^{20}$ = + 84,0° to + 87,5° calculated on the anhydrous basis (10 % w/v solution) |
| **Purity** | |
| Water | Not more than 2,0 % (Karl Fischer method) |
| Sulphated ash | Not more than 0,7 % |
| Other chlorinated disaccharides | Not more than 0,5 % |
| Chlorinated monosaccharides | Not more than 0,1 % |
| Triphenylphosphine oxide | Not more than 150 mg/kg |
| Methanol | Not more than 0,1 % |
| Lead | Not more than 1 mg/kg |

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**E 957 — THAUMATIN**

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|---|---|
| **Synonyms** | |
| **Definition** | |
| *Chemical name* | Thaumatin is obtained by aqueous extraction (pH 2,5 to 4) of the arils of the fruit of the natural strain of *Thaumatococcus daniellii* (Benth) and consists essentially of the proteins thaumatin I and thaumatin II together with minor amounts of plant constituents derived from the source material |
| *Einecs* | 258-822-2 |
| *E number* | E 957 |
| *Chemical formula* | Polypeptide of 207 aminoacids |
| *Relative molecular mass* | Thaumatin I 22209<br>Thaumatin II 22293 |
| *Assay* | Not less than 16% nitrogen on the dried basis equivalent to not less than 94% proteins (N × 5,8) |
| **Description** | Odourless, cream-coloured powder with an intensely sweet taste. Approximately 2 000 to 3 000 times as sweet as sucrose |
| **Identification** | |
| *Solubility* | Very soluble in water, insoluble in acetone |
| **Purity** | |
| *Loss on drying* | Not more than 9% (105°C to constant weight) |
| *Carbohydrates* | Not more than 3% expressed on dry weight basis |
| *Sulphated ash* | Not more than 2% expressed on dry weight basis |
| *Aluminium* | Not more than 100 mg/kg expressed on dry weight basis |
| *Arsenic* | Not more than 3 mg/kg expressed on dry weight basis |
| *Lead* | 3 mg/kg expressed on dry weight basis |
| *Microbiological criteria* | Total aerobic microbial count: Max 1 000/g *E. Coli:* absent in 1 g |

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**E 959 — NEOHESPERIDINE DIHYDROCHALCONE**

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|---|---|
| **Synonyms** | Neohesperidin dihydrochalcone, NHDC, hesperetin dihydrochalcone-4′-β-neohesperidoside, neohesperidin DC |
| **Definition** | |
| *Chemical name* | 2-O-α-L-rhamnopyranosyl-4′-β-D-glucopyranosyl hesperetin dihydrochalcone; obtained by catalytic hydrogenation of neohesperidin |
| *Einecs* | 243-978-6 |
| *E number* | E 959 |
| *Chemical formula* | $C_{28}H_{36}O_{15}$ |
| *Relative molecular mass* | 612,6 |
| *Assay* | Content not less than 96% on the dried basis |
| **Description** | Off white, odourless, crystalline powder having a characteristic, intensive sweet taste. Approximately between 1 000 and 1 800 times as sweet as sucrose |
| Identification | |
| *A. Solubility* | Freely soluble in hot water, very slightly soluble in cold water, practically insoluble in ether and benzene |
| *B. Ultraviolet absorption maximum* | 282 to 283 nm for a solution of 2 mg in 100 ml methanol |
| *C. Neu's test* | Dissolve about 10 mg of neohesperidine DC in 1 ml methanol, add 1 ml of a 1% 2-aminoethyl diphenyl borate methanolic solution. A bright yellow colour is produced |
| **Purity** | |
| *Loss on drying* | Not more than 11% (105°C, three huors) |
| *Sulphated ash* | Not more than 0,2% expressed on dry weight basis |
| *Arsenic* | Not more than 3 mg/kg expressed on dry weight basis |
| *Lead* | Not more than 2 mg/kg expressed on dry weight basis |
| *Heavy metals* | Not more than 10 mg/kg expressed as Pb on dry weight basis |

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**E 962 SALT OF ASPARTAME-ACESULFAME**

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|---|---|
| **Synonyms** | Aspartame-acesulfame, aspartame-acesulfame salt |
| **Definition** | The salt is prepared by heating an approximately 2:1 ratio (w/w) of aspartame and acesulfame K in solution at acidic pH and allowing crystallisation to occur. The potassium and moisture are eliminated. The product is more stable than aspartame alone |
| Chemical name | 6-Methyl-1,2,3-oxathiazine-4(3H)-one-2,2-dioxide salt of L-phenylalanyl-2-methyl-L-α-aspartic acid |
| Chemical formula | $C_{18}H_{23}O_9N_3S$ |
| Molecular weight | 457,46 |
| Assay | 63,0 % to 66,0 % aspartame (dry basis) and 34,0 % to 37 % acesulfame (acid form on a dry basis) |
| **Description** | A white, odourless, crystalline powder |
| **Identification** | |
| A. Solubility | Sparingly soluble in water, slightly soluble in ethanol |
| B. Transmittance | The transmittance of a 1 % solution in water determined in a 1 cm cell at 430 nm with a suitable spectrophotometer using water as a reference, is not less than 0,95, equivalent to an absorbance of not more than approximately 0,022 |
| C. Specific rotation | $[\alpha]_D^{20}$ = + 14,5° to + 16,5°<br>Determine at concentration of 6,2 g in 100 ml formic acid (15N) within 30 min of preparation of the solution. Divide the calculated specific rotation by 0,646 to correct for the aspartame content of the salt of aspartame-acesulfame |

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| **Purity** | |
| Loss on drying | Not more than 0,5 % (105 °C, four hours) |
| 5-Benzyl-3,6-dioxo-2-piperazineacetic acid | Not more than 0,5 % |
| Lead | Not more than 1 mg/kg |